K000026

510(k) Summary

Pursuant to 512(i)(3)(A) of the Food, Drug and Cosmetic Act, Apple Medical Corp. is required to submit with this Premarket Notification either an "...adequate summary of any information respecting safety and effectiveness or state that information will be made available upon request of any person." Apple Medical chooses to submit a summary of the safety and effectiveness information. The summary is as follows:

Trade Name: Apple Medical Uterine Sampler

Owner/Operator: Apple Medical Corporation
28 Lord Road, Unit 135
Marlboro, MA 01752
Registration # 1221923

Manufacturing/ Sterilization Site: B. Braun
824 Twelfth Avenue
Bethlehem, PA 18018

Device Generic Name: Uterine sampler

Classification: According to Section 513 of the Federal Food, Drug, and Cosmetic Act, the device classification is Class II, Performance Standards (21 CFR 884.1175).

Predicate Device: Pipet Curet
Marketed by:
Milex Products, Inc.
Chicago, IL 60631
K760264

Product Description:
The proposed Apple Medical Uterine Sampler consists of a plastic tube with a closed distal end, and a small distal side opening, and a plastic luer fitting at the proximal end. A 10cc disposable syringe is used to create a slight vacuum that will draw the sample (fluid or mucous) into the tube. The device includes a vacuum control valve that is activated once the distal tip of the device has been positioned, thus releasing the vacuum from the syringe to the sampler. This device is used to collect a sample of the uterine mucosal lining for analysis.

Indications for Use:
The Apple Medical Uterine Sampler is indicated for use use to gather samples for evaluation of uterine mucosal lining

Performance Testing:
Substantial equivalence for the proposed Apple Medical Uterine Sampler is based solely on a comparison of materials, design, specifications and principle of operation as compared to the predicate device. Therefore, there were no performance testing requirements for this submission.

Conclusion:
Based on the indications for use and technological/design characteristics, the Apple Medical Uterine Sampler device has been shown to be safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 31 2000

Mr. John C. Pulford
Director of Operations
Apple Medical Corporation
28 Lord Road, Unit 135
Marlboro, MA 01752

Re: K000026
Apple Medical One-Touch Uterine Sampler
Dated: January 4, 2000
Received: January 5, 2000
Regulatory Class: II
21 CFR 884.1175/Procode: 85 HHK

Dear Mr. Pulford:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

510(k) Number (if known): K000026

Device Name: Apple Medical One-Touch Uterine Sampler

Indications for Use:

The Apple Medical One-Touch Uterine Sampler is indicated for use to gather samples for evaluation of uterine mucosal lining for, but not limited to, the following purposes:

- Cancer screening.
- Endometrial dating.
- Determine response to estrogen replacement therapy.
- Bacterial culturing.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-the -Counter Use ____

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K000026